Remarks

Applicants request reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 112

Claim 24 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants have amended claim 24 to address this rejection.

Rejections under 35 U.S.C. § 102(b) and 103(a)

Claims 1-63 were rejected as allegedly being anticipated or obvious in view of the cited prior art. Applicants traverse the rejections and request that they be withdrawn for the reasons discussed below.

Independent Claim 1

Independent claim 1 has been amended to recite:

> a movable element having an inner surface that defines a portion of the chamber, the movable element being capable of moving in response to an external force applied to the exterior surface, wherein the external force causes the movable element to move toward the agent releasing orifices to increase pressure in the chamber and cause agent in the chamber to be expelled through the orifices.

(added language underlined.)

The action first rejects claim 1 as being allegedly anticipated by U.S. Patent No. 4,647,013 to Giachino (Giachino). Applicants disagree that Giachino teaches or suggests the subject matter of claim 1. Giachino discloses a silicon metering valve that is used to meter the flow of fluid, such as in a fuel injection system. In all of the embodiments disclosed in Giachino, the metering valve includes a chamber and one or more projections that can maintain a minimum spacing in the chamber. However, the projections are configured to close the outlet orifices of the valve when the upper membrane is moved toward the outlet orifices. For example, referring to FIGS. 15 and 15A of Giachino, there is shown a metering valve having a movable upper membrane 151 positioned opposite an outlet orifice 161. Fluid is allowed to flow through the outlet orifice 161 when the upper membrane 151 is moved away from the outlet orifice, as shown in FIG. 15A, but the valve closes when the upper membrane 151 moves toward the outlet orifice 161, as shown in FIG. 15. The valve is a passive device and does not have any means to pressurize the fluid and cause it to flow through the valve; fluid flow though the valve is caused

by an external fluid pump. Thus, the Giachino's metering valve does not have a movable element that pressurizes a chamber and causes fluid to be expelled through outlet orifices when the movable element is moved toward the outlet orifices, as recited in amended claim 1.

The action also rejects claim 1 as allegedly being obvious from U.S. Patent No. 6,405,934 to Hess (Hess) in view of Giachino. The action concedes that Hess does not teach projections that maintain a minimum spacing in the chamber, but contends that it would have been obvious to modify the aerosolizing element of Hess to include the projections as taught by Giachino "in order to prevent fluid from leaking through the orifices when the device is not activated." Applicants disagree that Hess in view of Giachino teaches or suggests the subject matter of claim 1 for the following reasons.

As discussed above, Giachino's projections close the valve and prevent fluid from being expelled from the outlet orifices when the upper membrane is moved toward the outlet orifice. Hence, even if Hess can be combined with Giachino, the combination would not meet the limitations of amended claim 1, and in particular, a movable element that causes agent to be expelled through outlet orifices when the movable element is moved toward the outlet orifices.

In addition, Hess teaches against the addition of projections as taught by Giachino. As pointed out by the action, the projections of Giachino prevent fluid from flowing through the outlet orifices when the device is not activated. When the device is activated, fuel (which is pressurized from an external fuel pump) is pumped through the metering valve.

In contrast to Giachino, Hess relies on the vibratory movement of the lower substrate 6 to push fluid outwardly through the corresponding outlet orifices 10. Indeed, the lower substrate 6 must be vibrated at relatively high frequencies (30 – 470 kHz) in order to obtain a desired substance output. (col. 6, lines 49-59.) As such, the outlet orifices cannot be sealed or covered by the projections during operation of the device. Consequently, if the Hess device is provided with projections as taught by Giachino, the projections would block the outlet orifices during operation and prevent fluid from being expelled through the outlet orifices. In other words, in normal operation, fluid is expelled outwardly through outlet orifices 10 as lower substrate pushes fluid toward the outlet orifices. If movement of the lower substrate causes the projections to close the outlet orifices, very little fluid, if any, would be expelled from the device.

MPEP § 2143.01(V) states that "If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or

motivation to make the proposed modification. Similarly, MPEP § 2143.01(VI) states that "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." In the present case, modifying Hess as taught by Giachino as proposed in the action would render Hess inoperable, i.e., the Hess device would be unsatisfactory for its intended purpose and it would change the principle of operation of the device. Thus, Hess in view of Giachino does not support a *prima facie* case of obviousness of claim 1.

The action also rejects claim 1 as allegedly being obvious from WIPO Publication No. 2002/074372A2 to Papania (Papania) in view of Giachino. As in the rejection of claim 1 based on Hess in view of Giachino, the action concedes that Papania does not teach projections that maintain a minimum spacing in the chamber, but contends that it would have been obvious to modify the aerosolizing element of Papania to include the projections as taught by Hess "in order to prevent fluid from leaking through the orifices when the device is not activated." For the same reasons that Hess in view of Giachino does not teach or suggest the subject matter of claim 1, Papania in view of Giachino does not teach or suggest the subject matter of claim 1.

Accordingly, for at least the foregoing reasons, the rejections of claim 1 should be withdrawn.

Independent claims 26 and 58

Independent claim 26 has been amended to recite:

> a disposable aerosolizing element disposed in the housing and capable of expelling aerosolized agent, the aerosolizing element comprising a chamber, agent releasing orifices, a movable element opposite the agent releasing orifices, and projections disposed in the chamber and configured to maintain a minimum spacing between the movable element and the orifices.

(added language underlined.)

Independent claim 58 has been amended to recite:

> wherein the aerosolizing element comprises a chamber, agent releasing orifices, a movable element opposite the agent releasing orifices, and projections disposed in the chamber and configured to maintain a minimum spacing between the movable element and the orifices.

Independent claim 26 was rejected as allegedly being obvious from Papania and as allegedly being obvious from Hess. Independent claim 58 was rejected as allegedly being

obvious from Papania. As discussed above, the action concedes that both Papania and Hess fail to teach an aerosolizing element having projections that maintain a minimum spacing in the chamber. Giachino does not make up for the deficiencies of Papania or Hess. Although Giachino teaches a metering valve having internal projections, the projections function to close the valve and prevent fluid flow. The devices of Papania and Hess are much different than the device Giachino because the outlet orifices must remain unsealed and uncovered by the projections during use; otherwise fluid would not be expelled through the outlet orifices. Thus, one skilled in the art would not combine the teachings of Papania or Hess with the teachings of Giachino.

Accordingly, for at least the foregoing reasons, the rejections of claims 26 and 58 should be withdrawn.

Independent claim 42

Independent claim 42, as amended, recites a handheld aerosolizing device, comprising:

> an aerosolizing element capable of expelling aerosolized agent, the aerosolizing element comprising a front portion having an opening extending completely therethrough, a rear portion having an opening extending completely therethrough, a chamber defined between the front and rear portion, an orifice plate aligned with the opening in the front portion, and a flexible diaphragm aligned with the opening in the rear portion opposite the orifice plate;
>
> an actuator coupled to the flexible diaphragm through the opening of the rear portion of the aerosolizing element to exert vibratory oscillations on the flexible diaphragm of the disposable aerosolizing element to aerosolize agent in the element, wherein aerosolized agent is expelled through orifices in the orifice plate and the opening in the front portion of the aerosolizing element; and
>
> wherein the aerosolizing element prevents the agent from contacting the actuator.

(added language underlined.)

Independent claim 42 was rejected as allegedly being obvious from Papania and as allegedly being obvious from Hess. Neither Papania nor Hess teaches or suggests an aerosolizing device comprising the features recited in amended claim 42. Accordingly, for at least the foregoing reasons, the rejections of claim 42 should be withdrawn.

Conclusion

The present application is in condition for allowance and such action is respectfully requested. The examiner is invited to telephone the undersigned attorney if any issues can be resolved to expedite allowance of the application.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Jeffrey B. Haendler/
Jeffrey B. Haendler
Registration No. 43,652